Version	Revision Date:	SDS Number:	Date of last issue: 2025/02/01
4.1	2025/02/23	100000015409	Date of first issue: 2023/06/19

SECTION 1. IDENTIFICATION

Substance name : AKEEGA 50 mg/500 mg film-coated tablets
Abiraterone acetate
Niraparib tosylate monohydrate

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Serious eye damage : Category 1

Skin sensitisation : Category 1

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland)
Short-term (acute) aquatic hazard	:	Category 1
Long-term (chronic) aquatic hazard	:	Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements :

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H341 Suspected of causing genetic defects.
H360 May damage fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H373 May cause damage to organs (male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P272 Contaminated work clothing must not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/

attention.
P363 Wash contaminated clothing before reuse.
P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
ABIRATERONE ACETATE	154229-18-2	>= 30 - < 50
cellulose	9004-34-6	>= 20 - < 30
NIRAPARIB TOSYLATE MONOHYDRATE	1613220-15-7	>= 5 - < 10
DODECYL SODIUM SULPHATE	151-21-3	>= 1 - < 5
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	>= 1 - < 5
TITANDIOXIDE	13463-67-7	>= 0.1 - < 1
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
COLLOIDAL ANHYDROUS SILICA	112945-52-5	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
Consult a physician.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).

Call a physician immediately.

Most important symptoms and effects, both acute and delayed	:	anemia constipation Increased blood pressure Nausea Fatigue Thrombocytopenia asthenia
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Hazardous combustion products	:	No information available.
Further information	:	No information available.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas. Avoid dust formation. Avoid breathing dust.
Environmental precautions	:	Should not be released into the environment. Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against	:	No data available

fire and explosion

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Store at room temperature.

Recommended storage temperature : 59 - 86 °F / 15 - 30 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ABIRATERONE ACETATE	154229-18-2	TWA	0.012 mg/m3	J&J OEL/PBOEL HHC
		STV	0,120 mg/100cm²	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 A	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3A., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development, Notation SKIN: has the potential for absorption via the skin.			
cellulose	9004-34-6	TWA	10 mg/m3	ACGIH
			10 mg/m3	ACGIH
		TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL

		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
NIRAPARIB TOSYLATE MONOHYDRATE	1613220-15-7	STV	0,010 mg/100cm²	J&J OEL/PBOEL HHC
		TWA	0.0034 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	3 B	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development, Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes			
DODECYL SODIUM SULPHATE	151-21-3	TWA	0.5 mg/m3	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B., Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes, Notation RSEN: has the potential to cause delayed allergic reactions (sensitization), such as shortness of breath, asthma and anaphylaxis.			
HYDROXYPROPYLMETHYLCELLULOSE (HPMC)	9004-65-3	TWA	10 mg/m3	ACGIH
TITANDIOXIDE	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL

				HHC
		TWA	10 mg/m3	ACGIH
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
COLLOIDAL ANHYDROUS SILICA	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3
		TWA	6 mg/m3 (Silica)	NIOSH REL

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet
Colour	:	yellow-orange, to, brown
Odour	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Density	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	:	None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 3,427 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 24.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

ABIRATERONE ACETATE:

Acute oral toxicity : LD50 (Mouse, male and female): > 2,000 mg/kg
Method: Acute oral toxicity
GLP: no

LD50 (Rat, male): > 400 mg/kg
Method: Acute oral toxicity
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No adverse effect has been observed in acute toxicity tests.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

NIRAPARIB TOSYLATE MONOHYDRATE:

Acute oral toxicity : Assessment: The component/mixture is moderately toxic after single ingestion.

DODECYL SODIUM SULPHATE:

Acute oral toxicity : LD50 Oral (Rat): 1,200 mg/kg
Method: OECD Test Guideline 401
Assessment: The component/mixture is moderately toxic after

single ingestion.

Acute inhalation toxicity : Assessment: The component/mixture is moderately toxic after short term inhalation.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,000 mg/kg

COLLOIDAL ANHYDROUS SILICA:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Components:

ABIRATERONE ACETATE:

Remarks : No data available

cellulose:

Species : Rabbit
Remarks : No skin irritation

DODECYL SODIUM SULPHATE:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Skin irritation

COLLOIDAL ANHYDROUS SILICA:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Components:

ABIRATERONE ACETATE:

Remarks : No data available

cellulose:

Species : Rabbit
Remarks : No eye irritation

NIRAPARIB TOSYLATE MONOHYDRATE:

Result : Eye irritation

DODECYL SODIUM SULPHATE:

Species	:	Rabbit
Result	:	Corrosive to eyes
Method	:	OECD Test Guideline 405

COLLOIDAL ANHYDROUS SILICA:

Species	:	Rabbit
Result	:	No eye irritation

Respiratory or skin sensitisation

Components:

ABIRATERONE ACETATE:

Remarks	:	No data available

cellulose:

Species	:	Guinea pig
Remarks	:	Did not cause sensitisation on laboratory animals.

NIRAPARIB TOSYLATE MONOHYDRATE:

Result	:	The product is a skin sensitiser, sub-category 1B.

DODECYL SODIUM SULPHATE:

Result	:	Not a sensitizer

Germ cell mutagenicity

Components:

ABIRATERONE ACETATE:

Genotoxicity in vitro	:	Method: Bacterial Reverse Mutation Test OECD 471 Result: negative GLP: yes Test system: Human lymphocytes Method: In vitro Mammalian Chromosome Aberration Test OECD 473 Result: negative GLP: yes
Genotoxicity in vivo	:	Species: Rat Application Route: Oral Method: In vivo Mammalian Erythrocyte Micronucleus Test OECD 474 Result: negative GLP: yes
Germ cell mutagenicity -	:	No evidence of mutagenicity based on in vitro and in vivo

Assessment studies and expert judgment.

NIRAPARIB TOSYLATE MONOHYDRATE:

Genotoxicity in vitro : Test system: Salmonella typhimurium
Method: Bacterial Reverse Mutation Test
Result: negative
GLP: yes

Test system: rat hepatocytes
Method: Other in vitro tests
Result: positive
GLP: no

Test system: Chinese hamster ovary cells
Method: In vitro Mammalian Chromosome Aberration Test
Result: positive
GLP: yes

Genotoxicity in vivo : Species: Rat
Method: In vivo Mammalian Erythrocyte Micronucleus Test OECD 474
Result: positive
GLP: yes

Germ cell mutagenicity - Assessment : Suspected of causing genetic defects, based on positive evidence obtained from in vitro and in vivo studies and expert judgment.

DODECYL SODIUM SULPHATE:

Genotoxicity in vitro : Method: OECD Test Guideline 471
Result: negative

Carcinogenicity

Components:

ABIRATERONE ACETATE:

Species : Mouse, male and female
Application Route : Oral
Exposure time : 26 w
Dose : 125-375-750 mg/kg body weight
Result : No evidence of carcinogenicity in animal studies.
GLP : yes

Species : Rat, male
Application Route : Oral
Exposure time : 104 w
Dose : 5-15-50 mg/kg body weight
Result : positive
GLP : yes
Remarks : The observed tumors do not appear to be relevant for men.

Species	:	Rat, female
Application Route	:	Oral
Exposure time	:	104 w
Dose	:	15-50-150 mg/kg body weight
Result	:	negative
GLP	:	yes

Carcinogenicity - Assessment	:	The observed tumors do not appear to be relevant for men.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Components:

ABIRATERONE ACETATE:

Effects on fertility	:	Species: Rat, male Application Route: Oral Dose: 30 - 300 mg/kg General Toxicity - Parent: NOAEL: < 30 mg/kg GLP: yes Remarks: Adverse effects on sexual function and fertility. Species: Rat, female Application Route: Oral Dose: 30 - 300 mg/kg General Toxicity - Parent: NOAEL: < 30 mg/kg GLP: yes Remarks: Adverse effects on sexual function and fertility.
Effects on foetal development	:	Species: Rat Application Route: Oral Dose: 10 - 30 - 100 mg/kg General Toxicity Maternal: NOAEL: < 10 mg/kg Teratogenicity: NOAEL: > 100 mg/kg Method: Developmental Toxicity GLP: yes Remarks: Did not show teratogenic effects in animal experiments.
Reproductive toxicity - Assessment	:	Sufficient evidence of reprotoxicity based on animals.
Teratogenicity - Assessment	:	No evidence of adverse effects on development.

NIRAPARIB TOSYLATE MONOHYDRATE:

Reproductive toxicity - Assessment : Limited evidence of reprotoxicity in animal studies and/or human studies.

Teratogenicity - Assessment : Limited evidence of adverse effects on development in animal studies and/ or human studies.

DODECYL SODIUM SULPHATE:

Effects on fertility : Remarks: negative

STOT - single exposure

Components:

ABIRATERONE ACETATE:

Remarks : No data available

DODECYL SODIUM SULPHATE:

Exposure routes : Inhalation
Assessment : The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

STOT - repeated exposure

Components:

ABIRATERONE ACETATE:

Exposure routes : Oral
Target Organs : male reproductive organs, female reproductive organs, Mammary gland, Pituitary gland, Adrenal gland
Assessment : The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.

NIRAPARIB TOSYLATE MONOHYDRATE:

Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

ABIRATERONE ACETATE:

Species : Rat, male and female
NOAEL : < 50 mg/kg
Application Route : Oral
Exposure time : 3m
Dose : 10d 250-750-2000->50-250-750
Subsequent observation period : 1m

GLP	:	yes
Species	:	Rat, male
NOAEL	:	< 50 mg/kg
Application Route	:	Oral
Exposure time	:	6m
Dose	:	50-150-400 mg/kg
GLP	:	yes
Species	:	Rat, female
NOAEL	:	50 mg/kg
Application Route	:	Oral
Exposure time	:	6m
Dose	:	50-150-400 mg/kg
GLP	:	yes
Species	:	Monkey, male and female
NOAEL	:	< 250 mg/kg
Application Route	:	Oral
Exposure time	:	3m
Dose	:	250-750-200mg/kg
Subsequent observation period	:	1m
GLP	:	yes
Species	:	Monkey, male and female
NOAEL	:	< 250 mg/kg
Application Route	:	Oral
Exposure time	:	9m
Dose	:	250-500-1000mg/kg
Subsequent observation period	:	4w
GLP	:	yes

NIRAPARIB TOSYLATE MONOHYDRATE:

Species	:	Rat, female
LOLo	:	750 mg/kg
Application Route	:	Oral
Exposure time	:	8d
Number of exposures	:	daily
Species	:	Rat
NOAEL	:	10 mg/kg
Application Route	:	Oral
Exposure time	:	1m
Number of exposures	:	daily
Species	:	Dog
NOAEL	:	3 mg/kg
Application Route	:	Oral
Exposure time	:	1m
Number of exposures	:	daily

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

Components:

NIRAPARIB TOSYLATE MONOHYDRATE:

Remarks : cytostatic

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

ABIRATERONE ACETATE:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.13 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes

NOEC (Oncorhynchus mykiss (rainbow trout)): 0.065 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.25 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition

Method: OECD Test Guideline 201
GLP: yes

EbC50 (Pseudokirchneriella subcapitata (green algae)): > 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.0 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.0011 mg/l
Exposure time: 32 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes

NOEC (Pimephales promelas (fathead minnow)): 0.000013 mg/l
Exposure time: 119 d
Test Type: Fish partial life cycle toxicity test
Method: OECD Test Guideline 229
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.00047 mg/l
Exposure time: 21 d
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211
GLP: yes

M-Factor (Chronic aquatic toxicity) : 1,000

Toxicity to microorganisms : NOEC (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h

Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

NOEC (Soil microorganisms): 250
Exposure time: 28 d
Test Type: Nitrogen transformation
Method: OECD Test Guideline 216
GLP: yes

Toxicity to soil dwelling organisms : Test Type: Acute toxicity
NOEC (Eisenia fetida (earthworms)): 500 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Test Type: Acute toxicity
EC50 (Eisenia fetida (earthworms)): > 1,000 mg/kg
Exposure time: 14 d
Method: OECD Test Guideline 207
GLP: yes

Test Type: Reproduction Test
NOEC (Springtail (Collembola)): 500 mg/kg
Exposure time: 28 d
Method: ISO 11267
GLP: yes

Test Type: Reproduction Test
EC50 (Springtail (Collembola)): 670 mg/kg
Exposure time: 28 d
Method: ISO 11267
GLP: yes

Plant toxicity : NOEC: 100 mg/kg
Exposure time: 14 d
Species: Terrestrial plants
Method: OECD Test Guideline 208
GLP: yes

EC50: > 100 mg/kg
Exposure time: 14 d
Species: Terrestrial plants
Method: OECD Test Guideline 208
GLP: yes

NIRAPARIB TOSYLATE MONOHYDRATE:

Toxicity to fish : Remarks: No data available

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 0.32 mg/l
End point: Growth rate
Exposure time: 72 h

Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.32 mg/l
End point: Biomass
Exposure time: 72 h
Test Type: Growth inhibition
Method: OECD Test Guideline 201
GLP: yes

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l
Exposure time: 32 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes

LOEC (Pimephales promelas (fathead minnow)): 0.10 mg/l
Exposure time: 32 d
Test Type: Fish early-life stage (FELS) toxicity test (OECD 210)
Method: OECD Test Guideline 210
GLP: yes

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.32 mg/l
Exposure time: 21 d
Test Type: Daphnia reproduction test
Method: OECD Test Guideline 211
GLP: yes

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : NOELR (activated sludge): <= 32 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
GLP: yes

DODECYL SODIUM SULPHATE:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 29 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : LC50 (Ceriodaphnia dubia (water flea)): 5.55 mg/l
Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 120 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) :

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 1 mg/l

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Toxicity to fish : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

ABIRATERONE ACETATE:

Biodegradability : aerobic
Inoculum: activated sludge
Result: Not readily biodegradable.
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

Stability in water : Test Type: aerobic
Degradation half life (DT50): 2.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: aerobic
Degradation half life (DT50): 2.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: aerobic
Degradation half life (DT50): 4.9 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1

Test Type: aerobic
Degradation half life (DT50): 3.3 Days
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2

NIRAPARIB TOSYLATE MONOHYDRATE:

Biodegradability : Remarks: No data available

Stability in water : Test Type: aerobic
Degradation half life (DT50): 225 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1

Test Type: aerobic
Degradation half life (DT50): 1.1 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: aerobic
Degradation half life (DT50): 349 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 1

Test Type: aerobic
Degradation half life (DT90): 863 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 1

Test Type: aerobic
Degradation half life (DT90): 8.3 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 1

Test Type: aerobic
Degradation half life (DT90): 1,160 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 1

Test Type: aerobic
Degradation half life (DT50): 155 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2

Test Type: aerobic
Degradation half life (DT50): 6.5 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: aerobic

Degradation half life (DT50): 469 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 2

Test Type: aerobic
Degradation half life (DT90): 979 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: total system 2

Test Type: aerobic
Degradation half life (DT90): 38 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: Fresh water 2

Test Type: aerobic
Degradation half life (DT90): 1,560 d
Method: OECD Test Guideline 308
GLP: yes
Remarks: sediment 2

DODECYL SODIUM SULPHATE:

Biodegradability : Result: Readily biodegradable.

Biochemical Oxygen Demand (BOD) : > 60 %(m)

Dissolved organic carbon (DOC) : > 70 %(m)

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Biodegradability : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

ABIRATERONE ACETATE:

Bioaccumulation : Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 625
Exposure time: 18 d
Method: OECD Test Guideline 305
GLP: yes

Species: Oncorhynchus mykiss (rainbow trout)
Bioconcentration factor (BCF): 576

Exposure time: 18 d
Method: OECD Test Guideline 305
GLP: yes

Partition coefficient: n-octanol/water : log Pow: > 6.20
Method: OECD Test Guideline 117
GLP: yes

NIRAPARIB TOSYLATE MONOHYDRATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -0.6
pH: 5
Method: OECD Test Guideline 107
GLP: yes

log Pow: 0.2
pH: 7
Method: OECD Test Guideline 107
GLP: yes

log Pow: 2.1
pH: 9
Method: OECD Test Guideline 107
GLP: yes

DODECYL SODIUM SULPHATE:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: 0.83 (68 °F / 20 °C)

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Bioaccumulation : Remarks: No data available

TITANDIOXIDE:

Partition coefficient: n-octanol/water : Remarks: No data available

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

Components:

ABIRATERONE ACETATE:

Distribution among environmental compartments : Adsorption/Soil
Koc: 269470 - 363061
Method: OECD Test Guideline 106

Adsorption/Activated sludge
Koc: 7705 - 11806
Method: OECD Test Guideline 106

Stability in soil : Test Type: Aerobic transformation in soil
Dissipation time: 18 Days
Method: OECD Test Guideline 307
GLP: yes
Remarks: soil 1

NIRAPARIB TOSYLATE MONOHYDRATE:

Distribution among environmental compartments : Adsorption/Soil
Koc: 34073 - 173972
Method: OECD Test Guideline 106

Adsorption/Activated sludge
Koc: 1597 - 3483
Method: OECD Test Guideline 106

DODECYL SODIUM SULPHATE:

Mobility : Remarks: No data available

Distribution among environmental compartments : Remarks: No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Distribution among environmental compartments : Remarks: No data available

COLLOIDAL ANHYDROUS SILICA:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Components:

ABIRATERONE ACETATE:

Results of PBT and vPvB assessment : Non-classified PBT substance

DODECYL SODIUM SULPHATE:

Environmental fate and pathways : No data available

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

Additional ecological information : No data available

HYDROXYPROPYLMETHYLCELLULOSE (HPMC):

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

COLLOIDAL ANHYDROUS SILICA:

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(abiraterone acetate)
Class : 9
Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077

Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (abiraterone acetate)
Class	:	9
Packing group	:	III
Labels	:	9
Packing instruction (cargo aircraft)	:	956
Packing instruction (LQ)	:	Y956
Packing instruction (EQ)	:	E1
Packing instruction (passenger aircraft)	:	956
Packing instruction (LQ)	:	Y956
Remarks	:	Special Provision A197: Environmentally hazardous substances, classified under UN 3077 or UN 3082, when transported in single or combination packagings containing a net quantity per single or inner packaging of 5 L or less for liquids or having a net mass of 5 kg or less for solids, are not subject to any other provisions of the IATA DGR provided the packagings meet the general provisions of IATA DGR 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of IATA DGR §2.6.10 are met.

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (abiraterone acetate)
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes
Remarks	:	2.10.2.7: Environmentally Hazardous Substances/Marine Pollutants, classified under UN 3077 or UN 3082, packaged in single or combination packagings containing a net quantity per single of inner packaging of 5L or less for liquids or having a net mass per single of inner packaging of 5kg or less for solids are not subject to the IMDG provided the packagings meet the general requirements of 4.1.1.1, 4.1.1.2, and 4.1.1.4 to 4.1.1.8., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of ADR/RID/ADN/IMDG §3.5.1.4 are met.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (abiraterone acetate)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes
Remarks	:	49 CFR 171.4 - Marine Pollutant Exception: Except when transporting aboard a vessel, the requirements of this subchapter do not apply to non-bulk packagings transported by motor vehicles, rail cars, and aircraft., This substance can be shipped under 'de minimi's quantities' provisions if the net quantity per inner package <= 1mL for liquids or <= 1g for solids and the net quantity per outer package does not exceed 100mL for liquids or 100g for solids and provided packaging provisions of 49 CFR 173.4b are met.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

cellulose	9004-34-6

Pennsylvania Right To Know

ABIRATERONE ACETATE	154229-18-2
cellulose	9004-34-6
D-Glucose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	64044-51-5
CROSPOVIDONE	9003-39-8
NIRAPARIB TOSYLATE MONOHYDRATE	1613220-15-7
DODECYL SODIUM SULPHATE	151-21-3

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including ABIRATERONE ACETATE, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances

CROSPOVIDONE	9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

cellulose	9004-34-6

Other regulations

Restricted to professional users.
Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / STV	:	STV: Surface Target Value
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory

concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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Date and Number Formats

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